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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/544,261	01/17/2006	Minoru Moriya	BY0006P	1503
210 7590 08/03/2009 MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907			EXAMINER CHANG, CELIA C	
			ART UNIT	PAPER NUMBER
			1625	
			MAIL DATE	DELIVERY MODE
			08/03/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

10/544,261

**Applicant(s)**

MORIYA ET AL.

**Examiner**

Celia Chang

**Art Unit**

1625

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 33-39, 42, 44, 45, 47-49 and 53-59 is/are pending in the application.
- 4a) Of the above claim(s) 47-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33-39, 42, 44, 45 and 53-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 5/27/09
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Amendment and response filed by applicants dated May 27, 2009 have been entered and considered carefully.

Claims 40-41, 43, 46, 50-52 have been canceled. Claims 47-49 stayed withdrawn. Claims 33-39, 42, 45, 53, and newly added 54-59 are pending.

2. The claim to the benefit of priority date of JP2003-032123 is denied. Applicants provided an English translation of the priority document. The translation document was compared with the instant application and it was noted that the two are not the "same invention" because the *specification and claims* are not the same. The priority document contained 5 tables and 83 compounds while the instant application contained 7 tables 89 compounds, thus, *additional material* have been added to the invention as originally filed i.e. the PCT/JP04/001326 is a CIP of JP2003-032123. The application date for the instant application is therefore the PCT filing date, Feb. 9, 2004.

3. The rejection of claim 33 under 35 USC 112 second paragraph is dropped in view of the amendment to the claim, however, a new matter rejection is made as following.

4. Claims 33, 54-57, 59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Please note that while the specification provided subgeneric description for Ar is a benzene ring, a pyridine ring, a pyrazine ring or a pyrimidine ring, unsubstituted or substituted with one or two substituents selected from Group  $\beta$ , as found on p. 16, line 24-25, none of the description corresponding to the preferred embodiment for Cy corresponding to the instantly amended Cy moieties, can be found. The instant amended scope of Cy is a *mix and match* of selected moieties among the many subgeneric scopes for which antecedent basis of the mixing

and matching is not found. Therefore, the amended claims are drawn to NEW MATTER for which no antecedent basis can be found in the specification. While the species as disclosed provided support for each individual Cy and its corresponding Ar and Y1-Y4 structure, such species only support the specific combination and failed to provide antecedent basis for any “subgeneric” inventive concept such as currently amended.

Removal of all new matter is required. In re Russmussen 210 USPQ 325.

5. The rejection of claim 33-34 under 35 USC 112 first paragraph for lacking sufficient enablement since only limited combination were enabled in comparison to the enormous mixing and matching of the Markush element, is maintained for reason of record and also applicable to the newly added claims 54-57, and 59.

As it was evidenced in the previous office action, the RN 1026906-40-0 anticipated the instant claims yet the specification provided no how to make of such a compound or the specification provided no evidence that such a compound would have the same utility as the exemplified compounds. There is no source identifiable with the scope of the claims wherein the starting material such as formula III of p. 18, was supported with sufficient Markush examples to warrant such a scope. The court has set forth that when the subject matter is highly unpredictable, for which the instant biological art is, more is required by way of exemplification for a broad scope. In re Fisher 166 USPQ 18.

Applicants argued by providing the names of the compounds that have been exemplified in the specification and such argument supports the rejection because all the examples as recited on pages 12-15 of the response fell within the scope of enablement as pointed out in the previous office action that “Markush compounds that exhibits biological activity (table 1) i.e. Cy is limited to “2-oxo-pyrrolidiny, 1-pyrazolyl, 1-imidazolyl, 1-triazolyl, 1-tetrazolyl, or pyridyl”.

6. The rejection of claims 33-44 (40-41 and 43 canceled) and 53 under 35 USC 102(c) over WO 2004/004714 is maintained for reason of record.

Please note that applicants’ argument with respect to that the WO 2004/004714 is not entitled to the priority date of the provisional filing since only during PCT application were the

spiroisofuranpiperidines enabled. Please note that the WO 2004/004714 designated US, in English and the filing date is July 3, 2003. The PCT filing date is prior art to the instant filing date of Feb. 9, 2004.

7. The rejection of claims 33-44 (40-41 and 43 canceled) 53 now applicable to claims 54-59 under 35 USC 103(a) over WO 2004/004714 is maintained for reason of record. Applicants provided no unexpected results as to the instant scope encompassed by the '714 reference having unexpected results.

8. The rejection of 33-44 (40-41 and 43 canceled) and 53 under 35 USC 102(g) over US 2006/0173027 now US patent 7,335,665, is maintained for reason of record.

Applicants argued that the '027 is not a patent and is not entitled to the priority date because it is a CIP. Please note that the requirement for 102(g) is that "the invention was made in this country by *another* inventor who had not *abandoned, suppressed, or concealed* it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other." Therefore, the evidence showing prior invention being disclosed in the pregrant is applicable to the 102(g) condition. Please note that the issued patent of the pregnant 2006/0173027, i.e. US 7,335,665 showed claims 19-29 at col. 109-110 which anticipated the instant claims have not been *abandoned, suppressed, or concealed* since the filing date of July 3, 2003.

In addition, the translation of the instant priority document indicated that the instant applicants are *in possession* of the instantly claimed invention on Feb. 9, 2004 since this is a CIP of the priority application. No evidence was made of record "what" was the scope corresponding to a "described" inventive concept with respective dates of conception and reduction to practice can be found for the instant application.

9. Applicants amendment necessitated the new ground of rejection.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**10.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*OACS/Chang  
July 30, 2009*

*/Celia Chang/  
Primary Examiner  
Art Unit 1625*